

ONE HUNDRED FIFTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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MEMORANDUM

July 17, 2018

To: Committee on Energy and Commerce Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Markup of H.R. 6351, Advancing U.S. Civil Nuclear Competitiveness and Jobs Act and H.R. 6378, Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018

On Wednesday, July 18th, 2018 at 1:00 p.m. in room 2123 of the Rayburn House Office Building, the full Committee will hold of markup of H.R. 6351, Advancing U.S. Civil Nuclear Competitiveness and Jobs Act and H.R. 6378, Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018.

I. H.R. 6351, ADVANCING U.S. CIVIL NUCLEAR COMPETITIVENESS AND JOBS ACT

A. Background

Section 57 of the Atomic Energy Act gives the Secretary of Energy authority to allow entities outside the United States to develop or produce special nuclear products in conjunction with the Department of State, the Nuclear Regulatory Commission, and the Department of Defense. The Department of Energy's (DOE) 10 CFR Part 810 regulations (Part 810) govern the process by which the federal government controls the flow of unclassified nuclear energy technology and assistance to foreign countries.¹ Part 810 establishes general authorizations that do not require U.S. government approvals. Some activities, however, require specific authorization under Part 810 from the Secretary of Energy. These activities include transferring sensitive nuclear technology to foreign countries, engaging in any form of uranium enrichment,

¹ Nuclear Innovation Alliance, *Enabling Nuclear Innovation - Part 810 Reform - Improving the Efficiency of U.S. Export Controls for Nuclear Energy Technologies* (Dec. 2017) (www.nuclearinnovationalliance.org/part810reform).

creating nuclear fuel that contains plutonium, and developing nuclear reactors designed to produce special nuclear material.²

On June 21, 2018, the Subcommittee on Energy marked up draft legislation by Rep. Johnson (R-OH) entitled the “Advancing U.S. Civil Nuclear Competitiveness and Jobs Act” and forwarded the bill to the full committee by a vote of 20-13. Rep. Johnson subsequently introduced H.R. 6351, the “Advancing U.S. Civil Nuclear Competitiveness and Jobs Act,” on July 12, 2018.

B. Summary of the Bill

Section 2 of the bill requires the Secretary of Energy to submit a report to the Congressional committees of jurisdiction on the current state of civilian nuclear commerce, and to offer recommendations on how the U.S. can improve its competitiveness. The report must also analyze how to apply Price-Anderson Act indemnification provisions to advanced nuclear technologies.

Section 3 institutes an expedited approval process for low proliferation risk reactor technologies. The expedited procedures do not apply to foreign countries designated as nuclear-weapon states. The committee print considered at the Subcommittee markup required the Secretary of Energy to issue a decision on an application within 30 days once the Secretary of State has received the required assurances from foreign countries. The introduced bill extends the application decision timeline to 45 days and requires that the interagency review process be completed before the timeline begins. This section also allows the Secretary of Energy to delegate authority to other DOE officials to sign off on Part 810 authorizations.

Section 4 requires the Comptroller General to submit a report to Congress one year after enactment, detailing the Secretary of Energy’s methodology for implementing the risk-pooling program established in Section 934(e) of the Energy Independence and Security Act of 2007. That program requires nuclear suppliers to conduct a retroactive assessment to cover the costs associated with covered incidents that occur outside of the U.S. and are not covered by Price-Anderson.³

II. H.R. 6378, PANDEMIC AND ALL-HAZARDS PREPAREDNESS AND ADVANCING INNOVATION ACT OF 2018

A. Background

H.R. 6378, the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018, introduced by Reps. Brooks (R-IN), Eshoo (D-CA), Walden (R-OR), and Pallone (D-NJ) would make changes to several programs related to public health and medical emergency

² Department of Energy, Office of Environment, Health, Safety and Security, *Atomic Energy Act and Related Legislation* (accessed May 17, 2018) (www.energy.gov/ehss/atomic-energy-act-and-related-legislation).

³ Energy Independence and Security Act of 2007, Pub. L. No. 110-140.

preparedness and response activities. H.R. 6378 builds on the discussion draft to make additional changes to several programs. A Subcommittee on Health hearing was held on this topic on June 6, 2018. Please refer to the [hearing memo](#) for more information.⁴ In addition, draft legislation was marked up in the Subcommittee on Health on June 27, 2018 and passed by voice vote. Please see the [markup memo](#) for more information.⁵

B. Summary of the Bill

Sec. 1. Short title.

- This section provides that the Act may be cited as the “Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018.”
 - This title has been changed from the title included in the discussion draft.

Sec. 2. Table of contents.

This section lists the table of contents.

TITLE I—STRENGTHENING NATIONAL PREPAREDNESS AND RESPONSE FOR PUBLIC HEALTH EMERGENCIES

Sec. 101. Coordination of preparedness for and response to all-hazards public health emergencies.

- This section amends the duties and functions of the Assistant Secretary for Preparedness and Response (ASPR) to include carrying out drill and operational exercises related to pandemic influenza and the emerging infectious disease program.
- This section expounds on ASPR’s existing logistics duties.
 - This provision is new to the introduced bill.
- Under current law, ASPR is required to develop and update a coordinated five-year budget plan with respect to chemical, biological, radiological, and nuclear agents. This section amends current law to also require that budget plan to include research and development activities related to the Biomedical Advanced Research and Development

⁴ House Committee on Energy and Commerce, *Examining the Reauthorization of the Pandemic and All-Hazards Preparedness Act*, 115th Cong. (June 6, 2018) (<https://democrats-energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/Dem-Memo-HE-Hrg-on-Examining-the-Reauthorization-of-the-Pandemic-and-All-Hazards-Preparedness-Act-2018-06-06.pdf>).

⁵ House Committee on Energy and Commerce, *Markup of H.R. __, Pandemic and All-Hazards Preparedness Reauthorization Act of 2018, H.R. 959, H.R. 1676, H.R. 3728, and H.R. 5385*, 115th Cong. (June 27, 2018) (https://democrats-energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/Dem-Memo-HE%20Markup%20of%20H.R.%20__2018-06-27.pdf).

Authority (BARDA) pandemic influenza and the emerging infectious disease programs established in Sec. 302.

- This section would change the development and updating of the five-year budget plan from yearly to every two years as well as require additional information be included in the plan.
 - This provision is new to the introduced bill.
- This section also requires ASPR to coordinate with the federal intelligence community to maintain a current assessment of national security threats and inform preparedness and response capabilities based on the range of the threats that have the potential to result in a public health emergency.
 - This provision is new to the introduced bill.
- This section requires ASPR to submit to the Energy and Commerce Committee weekly reports on the status and welfare of children who were separated from their parent or guardian as a result of the Administration's "zero tolerance" policy.
- This section would specify experience ASPR should utilize in carrying out emergency preparedness and response efforts.
 - This provision is new to the introduced bill.
- Under current law, ASPR is required to annually develop a Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy and Implementation Plan. This section would change that requirement to every two years.
 - This provision is new to the introduced bill.

Sec. 102. Public health emergency medical countermeasures enterprise.

- This section codifies the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE). It designates the ASPR as the Chair, identifies the members, and outlines the functions of the PHEMCE.
- This section would designate the members included in the discussion draft as voting and add three non-voting members, the Secretary of State, Director of National Intelligence, and Director of the Central Intelligence Agency.
 - This provision is new to the introduced bill.

Sec. 103. National Health Security Strategy.

- This section clarifies that the National Health Security Strategy should describe potential public health threats facing the nation and identify the processes to prepare to respond to such threats, consistent with other specified plans. The Strategy must include a description of the current public health workforce and its capabilities to improve medical surge capacity; considerations for zoonotic disease and disease outbreaks related to food and agriculture; and global health security and environmental hazards as they relate to domestic public health preparedness and response capabilities.
 - This section is new to the introduced bill.

Sec. 104. Improving emergency preparedness and response considerations for children.

- This section codifies and continues the work of the Children’s Preparedness Unit at the Centers for Disease Control and Prevention (CDC) to ensure needs of children are taken into consideration when preparing for and responding to public health emergencies.
 - This section is new to the introduced bill.

Sec. 105. Reauthorizing the National Advisory Committee on Children and Disasters.

- This section reauthorizes the National Advisory Committee on Children and Disasters — currently due to sunset on September 30, 2018—to sunset on that date in 2023.
- This section expounds upon the membership of the Advisory Committee, specify terms of its members, and require the Secretary to coordinate the activities with the National Advisory Committee established in Sec. 109 and Sec. 110.
 - This provision is new to the introduced bill.

Sec. 106. National Disaster Medical System.

- This section provides for direct hire authority, to sunset on September 30, 2021, in order to give the Secretary of Health and Human Services (HHS) more flexibility in hiring for the National Disaster Medical System (NDMS).
 - The sunset requirement is new to the introduced bill.
- It also includes greater flexibility in prepositioning response teams in advance of a public health emergency.
- This section makes deployed NDMS personnel or their families eligible for Public Safety Officers Benefits (PSOB) for line-of-duty death or serious disability and reauthorizes the NDMS through 2023, at \$57,400,000 per year.
- Finally, this section requires a joint review of the NDMS and an assessment of medical surge capacity relating to the availability of public health workforce for both widespread and multiple public health emergencies at one time.
 - This sunset requirement is new to the introduced bill.

Sec. 107. Volunteer Medical Reserve Corps.

- This section eliminates the provision in current law requiring the HHS Secretary to appoint a Director to oversee the Volunteer Medical Reserve Corps and reauthorizes the Corps through 2023, at \$6,000,000 per year.

Sec. 108. Continuing the role of the Department of Veterans Affairs.

- Current law requires the Department of Veterans Affairs (VA) to ensure that its medical centers are ready to protect patients and staff from a public health emergency, participate in NDMS, and develop and maintain a centralized system for tracking the current location and availability of pharmaceuticals, medical supplies, and medical equipment throughout the Department health care system in order to permit the ready identification and utilization of such pharmaceuticals, supplies, and equipment for response to a public health emergency. This section authorizes \$126,800,000 per year through FY 2023 to carry out these provisions.

Sec. 109. Authorizing the National Advisory Committee on Seniors and Disasters.

- This section establishes a National Advisory Committee on Seniors and Disasters to provide advice regarding state emergency preparedness and response activities for seniors as well as input with respect to the medical and public health needs of seniors related to all-hazards emergencies. This section would require the Secretary to coordinate the activities with the Advisory Committee reauthorized by Sec. 105 and established Sec. 110.
 - This section is new to the introduced bill.

Sec. 110. National Advisory Committee on Individuals with Disabilities in All-Hazards Emergencies.

- This section establishes a National Advisory Committee on Individuals with Disabilities to provide advice regarding state emergency preparedness and response activities for disabled individuals as well as input with respect to the medical and public health needs of the disabled community related to all-hazards emergencies. This section would require the Secretary to coordinate the activities with the Advisory Committee reauthorized by Sec. 105 and established Sec. 109.
 - This section is new to the introduced bill.

Sec. 111. Consideration for at-risk individuals.

- This section updates and aligns the term “at-risk individual” across the PAHPA framework to improve considerations, ensure consistency in considerations, and provide clarity throughout the framework.
 - This section is new to the introduced bill.

Sec. 112. Public health surveillance.

- This section incorporates public health surveillance into the National Health Security Strategy and requires that the surveillance capacity include emerging threats to pregnant and postpartum women and infants, including through monitoring birth defects, developmental disabilities, and other short-term and long-term adverse outcomes.
 - This section is new to the introduced bill.

Sec. 113. GAO study and report on disaster medical assistance teams.

- This section requires the Government Accountability Office (GAO) to assess the current mission readiness of ASPR’s disaster medical assistance teams (DMAT) to ensure sustained effective emergency response to current and emerging threats – natural and manmade.
 - This section is new to the introduced bill.

Sec. 114. Military and civilian partnership for trauma readiness grant program.

- This section establishes a grant program for military-civilian partnerships in trauma care that will allow both sectors to benefit from the others' expertise and experience. The grants will help develop integrated, permanent joint civilian and military trauma system training platforms to create and sustain an expert trauma workforce between periods of active combat.
 - This section is new to the introduced bill.

Sec. 115. Improvement of loan repayment program for prevention activities.

- This section reauthorizes a loan repayment program for the Centers for Disease Control and Prevention (CDC) to improve postdoctoral programs that train public health responders and leaders, such as the Epidemic Intelligence Service (EIS). These public health leaders are needed to mount successful responses to bioterror attacks, infectious diseases outbreaks, and other public health emergencies.
 - This section is new to the introduced bill.

Sec. 116. Report on adequate national blood supply.

- This section requires the HHS Secretary to submit to Congress a report containing recommendations related to maintaining an adequate national blood supply, including challenges associated with continuous recruitment of blood donors, ensuring adequacy of blood supply in the case of public health emergencies, and implementation of safety measures and innovation.
 - This section is new to the introduced bill.

TITLE II—OPTIMIZING STATE AND LOCAL ALL-HAZARDS PREPAREDNESS AND RESPONSE

Sec. 201. Public health emergencies.

- This section improves the existing Public Health Emergency Fund (PHEF) by identifying key authorities for which PHEF dollars may be used in the context of immediate support for the response activities for a public health emergency, or prior to a potential public health emergency. This section requires the HHS Secretary and GAO to conduct a review of the PHEF, including policies possibly needed to improve the PHEF, available fund resources, and the ability to use those resources during a public health emergency.
- This section also extends the authorization for the temporary reassignment of personnel during a public health emergency through 2023.
 - This provision is new to the introduced bill.

Sec. 202. Improving State and local public health security.

- This section reauthorizes the CDC Public Health Emergency Preparedness (PHEP) cooperative agreement through 2023 at \$670,000,000 per year and codifies the placement of the PHEP within CDC.
 - The codification of the PHEP at CDC is new to the introduced bill.

- This section also requires states to prioritize nursing homes in All-Hazards Public Health Emergency Preparedness and Response Plans, and to include in those plans information on how utilities plan to ensure that nursing homes return to functioning as soon as practicable following a disaster.
 - This provision is new to the introduced bill.

Sec. 203. Strengthening the hospital preparedness program.

- Updates language of statute to adopt currently used terminology.
- Amends current law to add an emergency medical service organization and emergency management organization as required members of HPP-funded coalitions, require coordination with a regional health care emergency system created by Sec. 206, and expands the withholding period for failure to reach benchmarks from one year to two years to allow time to repurpose funds.
 - These provisions are new to the introduced bill.

Sec. 204. Improving benchmarks and standards for preparedness and response.

- This section requires an evaluation of existing performance measures, benchmarks, and standards for the PHEP cooperative agreement program and the Healthcare Preparedness and Response Program.
 - This section is new to the introduced bill.

Sec. 205. Authorization of appropriations for revitalizing the Centers for Disease Control and Prevention.

- This section reauthorizes the bio surveillance and other preparedness capabilities of CDC at \$161,800,000 per year through 2023.

Sec. 206. Authorization of appropriations for Emergency System for Advanced Registration of Volunteer Health Professionals.

- This section extends the authorization of Emergency System for Advanced Registration of Volunteer Health Professionals (ESAR-VHP) at \$5,000,000 per year through 2023.

Sec. 207. Regional health care emergency preparedness and response systems.

- This section requires ASPR to develop guidelines in order to inform regional systems of hospitals, health care facilities, and public health facilities of varying levels of capabilities to treat patients affected by chemical, biological, radiological, or nuclear threats, including emerging infectious diseases in order to improve medical surge capabilities and capacity. This section also permits ASPR to establish a demonstration program to improve medical surge capacity by building and integrating regional medical response capabilities. Finally, this section requires GAO to report within two years on the progress made towards the implementation of the guidelines by health care facilities and

hospitals and requires subsequent recommendations to address challenges faced during implementation.

- This section is new to the introduced bill.

Sec. 208. National Academy of Medicine evaluation and report on the preparedness of hospitals, long-term care facilities, dialysis centers, and other medical facilities for public health emergencies.

- This section requires the HHS Secretary to enter into an arrangement with the National Academy of Medicine to evaluate the preparedness of hospitals, long-term care facilities, dialysis centers, and other medical facilities nationwide for public health emergencies, including natural disasters.
 - This section is new to the introduced bill.

Sec. 209. Limitation on liability for volunteer health care professionals.

- This section protects a health care professional from liability for harm caused by any act or omission if: (1) the professional is serving as a volunteer in response to a disaster and (2) the act or omission occurs during the period of the disaster, in the professional's capacity as a volunteer, and in a good faith belief that the individual being treated is in need of health care services.
 - This section is new to the introduced bill.

TITLE III—ACCELERATING MEDICAL COUNTERMEASURE ADVANCED RESEARCH AND DEVELOPMENT

Sec. 301. Strategic national stockpile and security countermeasure procurement.

- This section codifies ASPR's role in collaborating with the Secretary on the operation of the Strategic National Stockpile (SNS) with CDC and authorizes funding for the SNS at \$610,000,000 per year through FY 2023. It authorizes \$7,100,000,000 in funding for the Bioshield Special Reserve Fund for FY 2019 through FY 2028, and allows for funds to be provided by advance appropriations at a rate of not less than \$710,000,000 per year.
- This section also requires the Secretaries of HHS and Department of Homeland Security (DHS) to notify the Health, Education, Labor and Pensions Committee of the Senate, the Security and Government Affairs Committee of the Senate, and the Committee on Energy and Commerce and the Committee on Homeland Security of the House of Representatives of the material threat list on an annual basis, and promptly notify Congress each time there is a change to the threats on the list.
 - This section is new to the introduced bill.

Sec. 302. Biomedical advanced research and development authority.

- This section codifies authorities for the Director of the Biomedical Advanced Research and Development Authority (BARDA) to develop strategic initiatives for threats that pose a significant level of risk to national security, including antimicrobial resistant

pathogens. and updates BARDA other transactional authority (that is, authority to engage in transactions other than a contract, grant, or cooperative agreement with respect to projects).

- These provisions are new to the introduced bill.
- It authorizes \$536,700,000 in funding per year for BARDA through FY 2023. In addition, this section establishes a Pandemic Influenza Program at BARDA to support research and development activities to enhance a rapid response to pandemic influenza at \$250,000,000 in funding per year through FY 2023. Finally, this section establishes an Emerging Infectious Disease Program at BARDA to support research and development activities with respect to emerging infectious diseases at \$250,000,000 per year through FY 2023.

Sec. 303. Report on the development of vaccines to prevent future epidemics.

- This section requires the HHS Secretary to submit to Congress a report detailing the activities carried out by the Department to support the development of vaccines to prevent future epidemics, including work carried out through domestic and global public private partnerships and other collaborations intended to spur the development of such vaccines.
 - This section is new to the introduced bill.

TITLE IV—MISCELLANEOUS PROVISIONS

Sec. 401. Cybersecurity.

- This section amends a provision in current law to require that the next version of the National Health Security Strategy separately address cybersecurity threats. This section also designates ASPR as having the lead role in HHS for ensuring the ability of the health care sector to provide continuity of care during a cybersecurity incident.

Sec. 402. Miscellaneous FDA amendments.

- This section makes technical corrections to FDA’s emergency authorities that would clarify that material threat determinations may be the basis for Emergency Use Instructions under the Federal Food, Drug, and Cosmetic Act, and would clarify medical countermeasures subject to Emergency Use Authorities may legally be transported in interstate commerce. In addition, this section provides that when publishing information about qualified drug development tools—such as biomarkers and animal models—as required by law, FDA shall not disclose information that would compromise national security.

Sec. 403. Formal strategy relating to children separated from parents and guardians as a result of zero tolerance policy.

- This section requires ASPR to submit to the House Energy and Commerce Committee a formal strategy to reunify children who, as a result of the “zero tolerance” policy, were

separated from their parent or guardian and placed into a facility funded by HHS, and to address deficiencies identified by the previous work of the Committee, which began in 2014, regarding the oversight of, and care for, unaccompanied alien children in the custody of the Department.

Sec. 404. Biological threat detection.

- This section requires the Secretary to review federal biological threat detection programs, facilities exchange of information between such programs, and make recommendations to advance such systems. In addition, this section requires the development of guidelines for biological threat detection systems at the local level.
 - This section is new to the introduced bill.

Sec. 405. Strengthening Mosquito Abatement for Safety and Health.

- This section authorizes grants for mosquito control programs and reauthorizes CDC's Epidemiology-Laboratory Capacity Grants at \$40,000,000 per year through FY 2023.
 - This section is new to the introduced bill.

Sec. 406. Additional strategies for combating antibiotic resistance.

- This section codifies the Advisory Council on Combating Antibiotic-Resistant Bacteria, originally established by Executive Order 13676 in 2014, which will provide advice, information, and recommendations to the HHS Secretary regarding programs and policies intended to combat antibiotic-resistant bacteria.
 - This section is new to the introduced bill.

Sec. 407. Additional purposes for grants for certain trauma centers.

- This section updates previously authorized trauma center federal grant programs and furthers the core missions of trauma centers by permitting funding to be used to support essential personnel, costs associated with patient stabilization and transfer, coordination with local and regional trauma systems, surge capacity, and trauma education and outreach.
 - This section is new to the introduced bill.